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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,199	07/21/2003	Mary E. Abood		7735

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Mary E. Abood
Forbes Norris ALS/MDA Research Center
Suite 416
2351 Clay St.
San Francisco, CA 94115

EXAMINER	
STANDLEY, STEVEN H	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,199	ABOOD, MARY E.	
	Examiner	Art Unit	
	Steven H. Standley	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3 and 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election ***with traverse*** of Group II (claims 1, 3 and 4), directed at a method of screening and a therapeutic method in the reply filed on 2/10/05 is acknowledged. Applicant argues that because the classification of the inventions is the same, there is no search burden. The examiner has considered applicant's arguments, however they are deemed unpersuasive. The inventions test different subjects (i.e., refer to different patient populations) and are directed at different goals as made of record in the requirement for restriction. Therefore they are distinct and would require searching that is non-coextensive.

Claim Objections

Claims 1 is objected to because of the following informalities: Claim 1 contains reference to 'ALS' and 'MND' without first disclosing the meaning of the acronym. In order to make the description of the invention more clear, the first claim that mentions 'ALS' or MND (claim 1) should fully express the phrase, and be followed by parentheses, which identify the acronym to be used in the following claims. Appropriate correction is required.

Claim 4 is objected to because of the following informalities: Claim 4 does not have a "." at the end of the sentence.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3 and 4 are to a method of screening useful to identify compounds affecting motor function in ALS or MND patients, and a therapeutic method of useful for a patient determined to be suffering from one or more abnormal motor symptoms of ALS (claim 3) claiming several modes of administration (claim 4). Both methods recite either "administering an anandamide/cannabinoid receptor/acceptor agonist" or "administering a predetermined amount of anandamide..." Both methods also recite a mammal or patient having at least one, or more motor functions or symptoms related to ALS or MND.

However, the specification teaches the administration of only *a one* anandamide/cannabinoid/receptor/acceptor agonists (THCΔ9; note that Dronabinol is THC Δ9), and few detectable motor functions related to ALS (as measured by a rotorod endurance test in example 1, ALS Functional Ratings Scale, Forced Vital Capacity, and analog scales measuring muscle fasciculations and spasms in human patients). Accordingly, because of the absence of adequate species taught with respect to the *genus* "anandamide/cannabinoin/receptor/accetpor agonists," and the genera "motor function," or "abnormal symptom," the specification does not provide adequate

description of the claimed genera. This is because unknown and undescribed "agonists," "motor functions," and "abnormal symptoms are encompassed by the claims as currently recited.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

The skilled artisan cannot envision the anandamide/cannabinoid agonists, nor the "detectable motor functions," or "abnormal symptoms" encompassed by the methods claimed, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The detectable signal or signaling pathway itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. Therefore, only specific "motor functions," "abnormal symptoms," and "agonists" but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112,

first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step relating back to the preamble; for instance how does the "motor function" have to change to indicate that the compound affects a motor function as compared in patients (i.e., an increase in function as compared to control).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Della Valla et al. (1999; US patent number 5990170).

In claim 3, applicant recites "A therapeutic method useful for a patient determined to be suffering from one or more symptoms of Amyotrophic Lateral Sclerosis or Motor

Neuron Disease, comprising administering an amount of anandamide/cannabinoid receptor/acceptor agonist ...effective to promote normal motor function to the patient."

The invention is anticipated by Della Valla et al. Della Valla et al. teach that amides of mono and bicarboxylic aliphatic acids with amino alcohols and aminoethers selectively bind to and activate cannabinoid peripheral receptors (CB2; col. 4 lines 48-51). Della Valla et al. teach that the amides are suitable for the treatment of deseases connected with an anomalous modulation of CB2 cannabinoid peripheral receptor (col. 37, lines 16-22). Della Valla et al. disclose that the amides are useful in the treatment of diseases including muscular spasm connected with degenerative diseases of the nervous system, such as multiple sclerosis and ALS (col. 37, lines 27-34). Finally, Della Valla et al teach that the amides may be administered in therapeutically effective formulations (col. 37, lines 54-67 through col 38, lines 1-12)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller et al, (2000, US patent 6017965), and in further view of Della Valla et al.

The applicants method of screening is recited as "a screening method, useful to identify compounds affecting motor function in ALS or MND patients comprising:

administering [a cannabinoid agonist] to a mammal having at least one detectable motor function related to an ALS or MND symptom; detecting any motor function change and evaluating any such motor change with respect to a determinable motor function."

Mueller et al teach a method of screening for compounds useful in treating a "neurological disease or disorder such as...amyotrophic lateral sclerosis [abstract, Mueller et al]" wherein mice "were injected with test compound and placed on a knurled rod which rotated at a speed of 6 rpm [column 80, last paragraph of Mueller et al.] Mice were then evaluated for acute motor impairment (column 81, Mueller et al.). Mueller et al. further state that "compound 1 produced acute motor impairment in Frings [or CF1 mice; mouse models of epilepsy; Column 81, top paragraph] mice ." On page 2, line 3 of the instant specification teaches that a symptom associated with ALS is "involuntary muscle contraction." Frings mice exhibit epilepsy, a hallmark of which is involuntary muscle contraction (col. 77, lines 31-32).

Therefore, Mueller et al. describe a screening method useful to identify compounds affecting motor function in ALS or MND patients comprising: administering a compound to a mammal having at least one detectable function related to an ALS or MND symptom (in the case of Mueller et al., involuntary muscle contraction) and then detecting any such motor change with respect to determinable motor function. In the case of Muller et al., the determinable motor function is to "maintain equilibrium for long periods of time [Mueller et al., column 80, last paragraph]" by remaining on the rotorod. Mueller et al. teach that "compound 1[shown between columns 9 and 10 of Mueller et al.]" affects motor function as measured by rotorod in 2 different animal models of

epilepsy, impairing motor function in both models compared to untreated animals (Mueller et al., column 80, paragraphs 1-2). Therefore, compound 1 intrinsically affects motor function and would reasonably be expected to affect motor function in "a mammal" or "in ALS or MND patients" as recited in claim 1.

Mueller et al. do not teach administration of an anandamide/cannabinoid/receptor agonist to affect motor function in a mammal exhibiting one or more symptoms of ALS or MND.

Della Valla et al teach administration of an anandamide/cannabinoid/receptor agonist to affect motor function in a mammal having one or more symptoms of ALS or MND. In Column 37, lines 30-35, Della Valla et al. contemplate therapeutic treatment of "diseases...[associated with] muscle spasm connected with degenerative diseases of the nervous system, such as multiple sclerosis and amyotrophic lateral sclerosis."

It would be obvious to the person of ordinary skill in the art at the time the invention was made to modify the screening method of Meuller et al. by utilizing the cannabinoid agonists of Della Valla et al. The motivation to combine the method of Mueller et al. with the use of cannabinoid agonist taught in Della Valla et al. is given by Della Valla, wherein Della Valla et al. state that "[CB2 agonists] are particularly useful in the treatment of diseases connected with the modulation of said receptor such as [diseases associated with] muscle spasm...such mutltiple sclerosis and amyotrophic lateral sclerosis [lines 27-33, column 37, Della Valla et al.]." Therefore one normally skilled in the art would be motivated to test other cannabinoid compounds using a method of screening that tested motor function as described in Mueller et al. The

person of ordinary skill in the art would have expected success because similar methods were already being performed to discover the activity of various compounds at the time the invention was made.

Summary

Any inquiry concerning this communication should be directed toward examiner Steven Standley (Ph: 571-272-3432). The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the Steven Standley fail, the examiners' supervisor, Anthony Caputa, can be reached at (571 272-0829).

Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (toll free) 866-217-9197.

Steven H. Standley, Ph.D.

2/16/2005

Bridget E. Bunner